

EXHIBIT A

943 F.3d 1243

United States Court of Appeals, Ninth Circuit.

PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND, third-party healthcare payor fund; Annie M. Snyder, a California consumer; Rickey D. Rose, a Missouri consumer; John Cardarelli, a New Jersey consumer; Marlyon K. Buckner, a Florida consumer; Sylvie Bigord, a Massachusetts consumer, on behalf of themselves and all others similarly situated, Plaintiffs-Appellants,
v.

TAKEDA PHARMACEUTICALS COMPANY LIMITED, a Japanese Corporation; **Takeda Pharmaceuticals U.S.A.**, fka Takeda Pharmaceuticals North America, Inc., an Illinois corporation; Eli Lilly and Company, an Indiana corporation, Defendants-Appellees.

No. 18-55588

Argued and Submitted June 6, 2019 Seattle, Washington

Filed December 3, 2019

Synopsis

Background: Health insurer and consumers filed putative class action against pharmaceutical company, alleging civil Racketeer Influenced and Corrupt Organizations Act (RICO) violations based on company's refusal to change warning label on diabetes drug or otherwise inform consumers after company learned that drug caused increased risk of bladder cancer. The United States District Court for the Central District of California, [Stephen V. Wilson](#), J., dismissed the action. Plaintiffs appealed.

[Holding:] The Court of Appeals, [Bea](#), Circuit Judge, in a matter of first impression, held that plaintiffs plausibly alleged the element of proximate cause, as required to support civil RICO claim.

Reversed and remanded.

West Headnotes (14)

[1] Federal Courts

🔑 Pleading

The Court of Appeals reviews de novo the district court's grant of a motion to dismiss for failure to state a claim. [Fed. R. Civ. P. 12\(b\)\(6\)](#).

[2] Federal Civil Procedure

🔑 Clear or certain nature of insufficiency

Federal Civil Procedure

🔑 Matters deemed admitted; acceptance as true of allegations in complaint

In deciding a motion to dismiss for failure to state a claim, a court takes factual allegations in the complaint as true, and will grant the motion only if it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim which would entitle him to relief. [Fed. R. Civ. P. 12\(b\)\(6\)](#).

[3] Racketeer Influenced and Corrupt Organizations

🔑 Constitutional and statutory provisions

Although the Racketeer Influenced and Corrupt Organizations Act (RICO) statute was originally enacted to combat organized crime, it is also used for everyday fraud cases brought against respected and legitimate enterprises. [18 U.S.C.A. § 1962](#).

[4] Racketeer Influenced and Corrupt Organizations

🔑 Elements of violation in general

To recover for a civil Racketeer Influenced and Corrupt Organizations Act (RICO) violation, a plaintiff must prove that the defendant engaged in (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. [18 U.S.C.A. § 1962](#).

[5] **Racketeer Influenced and Corrupt Organizations**

🔑 Business, property, or proprietary injury; personal injuries

Racketeer Influenced and Corrupt Organizations

🔑 Causal relationship; direct or indirect injury

To allege civil Racketeer Influenced and Corrupt Organizations Act (RICO) standing, a plaintiff must show: (1) that his alleged harm qualifies as injury to his business or property; and (2) that his harm was by reason of the RICO violation. 18 U.S.C.A. § 1964(c).

[6] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

To support a claim for a civil Racketeer Influenced and Corrupt Organizations Act (RICO) violation, both proximate and but-for causation must be shown. 18 U.S.C.A. § 1964(c).

[7] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

The requirement of proximate cause to prove a civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim seeks to limit a person's responsibility to the consequences of that person's own acts. 18 U.S.C.A. § 1964(c).

[8] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

The proximate cause requirement necessary to support a Racketeer Influenced and Corrupt Organizations Act (RICO) claim generally bars suits for alleged harm that is too remote from the defendant's unlawful conduct. 18 U.S.C.A. § 1964(c).

[9] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

The proximate cause requirement for a civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim demands some direct relation between the injury asserted and the injurious conduct alleged. 18 U.S.C.A. § 1964(c).

[10] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

The less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors, for purpose of determining proximate causation in a civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim. 18 U.S.C.A. §§ 1962, 1964(c).

[11] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

Proximate cause in a civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim is a flexible concept that does not lend itself to a black-letter rule that will dictate the result in every case. 18 U.S.C.A. §§ 1962, 1964(c).

[12] **Racketeer Influenced and Corrupt Organizations**

🔑 Causal relationship; direct or indirect injury

Consumers who purchased diabetes drug and health insurer who reimbursed consumers plausibly stated the element of proximate cause, as required to support civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim against pharmaceutical company, where they alleged that, but for the pharmaceutical company's failure to change warning label on diabetes drug or otherwise inform consumers after manufacturer learned that drug caused increased risk of bladder cancer, they would not have paid for the drug. 18 U.S.C.A. §§ 1962, 1964(c).

1 Cases that cite this headnote

[13] Racketeer Influenced and Corrupt Organizations

🔑 Causal relationship; direct or indirect injury

In determining the proximate cause element of a civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim, the court considers the risk of multiple recoveries by plaintiffs at different levels of injury from the defendant's acts. 18 U.S.C.A. §§ 1962, 1964(c).

[14] Racketeer Influenced and Corrupt Organizations

🔑 Causal relationship; direct or indirect injury

In determining the proximate cause element of a civil Racketeer Influenced and Corrupt Organizations Act (RICO) claim, a court considers whether holding the defendant liable in the case justifies the general interest of deterring injurious conduct or whether there are more directly injured victims that the court can count on to hold the defendant liable. 18 U.S.C.A. §§ 1962, 1964(c).

Attorneys and Law Firms

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Appeal from the United States District Court for the Central District of California, Stephen V. Wilson, District Judge, Presiding, D.C. No. 2:17-cv-07223-SVW-AS

Before: Carlos T. Bea, Jacqueline H. Nguyen, and Paul J. Watford*, Circuit Judges.

OPINION

BEA, Circuit Judge:

*1246 Today we confront an issue of first impression in our circuit, and one that has caused an apparent circuit split among four of our sister circuits: In civil actions brought under the Racketeer Influenced and Corrupt Organizations Act (“RICO”) against pharmaceutical companies, do patients and health insurance companies who reimbursed patients adequately allege the required element of proximate cause where they allege that, but for the defendant’s omitted mention of a drug’s known safety risk, they would not have paid for the drug?

I. FACTUAL BACKGROUND

This appeal arises from a putative class action against Takeda Pharmaceuticals USA, Inc., its parent company Takeda Pharmaceutical Company Ltd., and Eli Lilly & Co. (collectively, “Defendants”). Together, Defendants developed and marketed a drug named *Actos*. *Actos* was intended to lower blood sugar in type 2 diabetics. Defendants obtained Food and Drug Administration (“FDA”) approval for *Actos* in 1999. The plaintiffs allege that despite learning through multiple studies over the next several years that *Actos* increased a patient’s risk of developing bladder cancer, Defendants refused to change *Actos*’s warning label or otherwise inform the public of such risk. Further, the plaintiffs allege that Defendants convinced the FDA that studies revealing that *Actos* increased the risk of bladder cancer were wrong. Defendants are alleged to have actively misled prescribing physicians, consumers, and third-party payors into believing that *Actos* did not increase a person’s risk of developing bladder cancer. Defendants did all of this, the plaintiffs allege, simply to increase their profits from the sale of *Actos*.

On September 17, 2010, after further studies of *Actos* revealed an increased risk of bladder cancer, the FDA

announced that it was conducting a safety review of [Actos](#). On June 15, 2011, the FDA released an official warning to the public that [Actos](#) may be linked to bladder [cancer](#) in patients who use it over prolonged periods of time. Following the FDA's official warning, Defendants changed [Actos's](#) warning label to warn of a bladder [cancer](#) risk. The sales of [Actos](#) are alleged to have dropped shortly after the FDA issued its alert in 2010, and then again when the FDA issued its official warning in 2011, by a total of approximately 80%.

A group of patients who developed bladder [cancer](#) after ingesting [Actos](#) and their family members then brought personal injury and wrongful death claims against Defendants in the Western District of Louisiana. After a 37-day trial in 2014, the jury returned a verdict in favor of the plaintiffs, but the parties later agreed to a global settlement program for all eligible personal injury claimants who used [Actos](#) before December 1, 2011 and had been diagnosed with bladder [cancer](#). *In re Actos (Pioglitazone) Prods. Liab. Litig.*, MDL No. 6:11-MD-2299, 274 F. Supp. 3d 485, 503 (W.D. La. 2017).¹

The present action was also originally filed in the Western District of Louisiana. But in late 2017, the parties stipulated to transfer the case to the Central District of California. The plaintiffs in this case comprise five individual patients from different states (collectively, "Patients") and Painters and Allied Trades District Council 82 *1247 Health Care Fund ("Painters Fund") (together, "Plaintiffs").

Painters Fund is a third-party payor ("TPP") of health and welfare benefits to covered members and their families. As a TPP, Painters Fund reimburses its members' claims for drugs, including [Actos](#), submitted by pharmacies and healthcare providers covered by its plan. Painters Fund "relies on each member to submit claims for prescription medications that are medically reasonable and necessary for treatment," with the expectation that patients and their prescribing physicians will "make informed decisions about which drugs will be prescribed and, in turn, submitted to [Painters Fund] for reimbursement." Painters Fund "has the authority to determine which drugs are covered under its plan, although, [it] entrusts the administration of claims and formulary determinations to Prime Therapeutics, LLC, based in Eagan, Minnesota."²

Patients are individuals with [type 2 diabetes](#) who were prescribed [Actos](#) by their physicians and who took [Actos](#) to help lower their blood sugar. Each patient paid an out-of-

pocket sum for [Actos](#). Patients each allege that neither they nor their physicians knew about [Actos's](#) risk of bladder [cancer](#) when they began taking the drug and that they immediately stopped taking [Actos](#) once they learned that it increased their risk of developing bladder [cancer](#). Patients also allege that they never would have purchased [Actos](#) had they known that it increased their risk of developing bladder [cancer](#), and thus, that they never would have submitted claims for reimbursement for purchases of [Actos](#) to their respective TPPs. Only one patient, Annie Snyder from California, alleges that prior to starting her prescription, she read and relied upon the [Actos](#) label. But Plaintiffs generally allege that Patients relied on Defendants' misrepresentations about [Actos](#), by act or omission, in purchasing the drug, that physicians relied on such misrepresentations in prescribing [Actos](#) for their patients, and that TPPs relied on such misrepresentations in agreeing to pay for [Actos](#) prescriptions for their members.

Plaintiffs seek to represent a class of similarly situated patients and TPPs "who paid or incurred costs for the drug [Actos](#), for purposes other than resale, between 1999, i.e., when the drug was approved, and the present," excluding "those consumers who are presently seeking a personal injury claim arising out of their use of [Actos](#)." Plaintiffs argue that Defendants conspired to commit mail and wire fraud under 18 U.S.C. §§ 1341, 1343 by intentionally misleading physicians, consumers, and TPPs to believe that [Actos](#) did not increase a person's risk of developing bladder [cancer](#). Plaintiffs seek to recover economic damages under RICO for the payments they made to purchase [Actos](#) under the assumption that it was a safe drug, which they allege they would not have purchased had they known that [Actos](#) increases a person's risk of developing bladder [cancer](#) (this is called the "quantity effect theory" of damages).³ Plaintiffs do not, however, seek to recover economic or non-economic damages caused by any person's actual ingestion of [Actos](#).

The district court dismissed with prejudice Plaintiffs' RICO claims under *1248 [Federal Rule of Civil Procedure 12\(b\)\(6\)](#) in a single paragraph, holding that Plaintiffs failed adequately to allege facts sufficient to establish that Defendants' acts and omissions were the proximate cause of their claimed damages. This appeal followed.⁴

II. ANALYSIS

A. Standard of Review

RICO Bus.Disp.Guid 13,268, 19 Cal. Daily Op. Serv. 11,605...

[1] [2] We review *de novo* the district court’s grant of a Rule 12(b)(6) motion to dismiss. *Bain v. Cal. Teachers Ass’n*, 891 F.3d 1206, 1211 (9th Cir. 2018). We take all of Plaintiffs’ factual allegations as true, and we may affirm the dismissal “only if it appears beyond doubt that [Plaintiffs] can prove no set of facts in support of [their] claim[s] which would entitle [them] to relief.” *Id.* (internal quotation marks omitted).

it “demand[s] ... some direct relation between the injury asserted and the injurious conduct alleged.” *Holmes*, 503 U.S. at 268, 112 S.Ct. 1311.

[10] This “direct relation” requirement is based upon three practical factors, stated in *Holmes*:

B. Plaintiffs’ RICO Claims

[3] [4] The crux of Plaintiffs’ complaint rests on their civil RICO claims. Although the RICO statute was originally enacted to combat organized crime, “it has become a tool for everyday fraud cases brought against respected and legitimate enterprises.” *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499, 105 S.Ct. 3275, 87 L.Ed.2d 346 (1985) (internal quotation marks omitted). Broadly speaking, there are two parts to a civil RICO claim. The civil RICO violation is defined under 18 U.S.C. § 1962,⁵ while “RICO standing” is defined under 18 U.S.C. § 1964(c). The district court dismissed Plaintiffs’ RICO claims only for lack of standing, and thus we address only that portion of Plaintiffs’ RICO claims.

[5] To allege civil RICO standing under 18 U.S.C. § 1964(c), a “plaintiff must show: (1) that his alleged harm qualifies as injury to his business or property; and (2) that his harm was ‘by reason of’ the RICO violation.” *Canyon County v. Syngenta Seeds, Inc.*, 519 F.3d 969, 972 (9th Cir. 2008). Defendants do not dispute that Plaintiffs have alleged an injury to their business or property. Rather, as the district court held, Defendants argue that Plaintiffs have failed to allege that their harm was “by reason of” the alleged RICO violation because they have failed to allege the claimed RICO violation was the proximate cause of their claimed losses.

1. Supreme Court Precedent

[6] [7] [8] [9] The Supreme Court has interpreted the phrase “by reason of” in 18 U.S.C. § 1964(c) to require, as elements for a civil RICO recovery, both proximate and but-for causation.⁶ *Holmes v. Sec. Inv’r Prot. Corp.*, 503 U.S. 258, 268, 112 S.Ct. 1311, 117 L.Ed.2d 532 (1992). The requirement of proximate cause seeks to “limit a person’s responsibility for the consequences of that person’s own acts.” *Id.* Put another way, “the proximate-cause requirement generally bars suits for alleged harm that is ‘too remote’ from the defendant’s *1249 unlawful conduct.” *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 133, 134 S.Ct. 1377, 188 L.Ed.2d 392 (2014). Thus,

First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

Id. at 269–70 (internal citations omitted). The Supreme Court has applied the *Holmes* factors, along with its direct relation requirement, in each of its decisions addressing proximate cause for civil RICO claims.

In *Anza v. Ideal Steel Supply Corp.*, the plaintiff—a steel mill product retailer in New York City—alleged that one of its retail competitors caused it economic harm by failing to charge customers applicable New York state sales taxes, thereby defrauding the New York state tax authority. 547 U.S. 451, 457–58, 126 S.Ct. 1991, 164 L.Ed.2d 720 (2006). This conduct, the plaintiff alleged, allowed the defendant to offer lower prices and attract more customers, which in turn caused the plaintiff to lose customers and profit. *Id.* The district court dismissed the plaintiff’s complaint under Rule 12(b)(6) for failure to plead proximate cause, but the Second Circuit vacated the district court’s judgment, holding that the plaintiff

had adequately pleaded that the defendant proximately caused its damages. *Id.* at 455, 126 S.Ct. 1991. The Supreme Court then reversed the Second Circuit’s judgment and held that the plaintiff failed to satisfy the requirement to allege proximate cause under RICO because the “direct victim of this conduct was the State of New York, not [the plaintiff].” *Id.* at 458, 126 S.Ct. 1991. Indeed, “[i]t was the State that was being defrauded and the State that lost tax revenue as a result.” *Id.* Although the plaintiff alleged that it suffered its own harms by losing customers and profits through the defendant’s failure to tax its customers, the plaintiff’s asserted harms were “entirely distinct from the alleged RICO violation (defrauding the state),” and thus the plaintiff’s allegations failed the Supreme Court’s direct relation requirement for the element of proximate cause. *Id.*

Likewise, in *Hemi Group, LLC v. City of New York*, the Supreme Court reversed the Second Circuit’s holding that the plaintiffs had sufficiently alleged damages proximately caused by the defendants’ actions under RICO to survive dismissal under Rule 12(b)(6). 559 U.S. 1, 4–5, 130 S.Ct. 983, 175 L.Ed.2d 943 (2010). There, the City of New York (the “City”), which imposed a \$1.50-per-pack tax on each pack of cigarettes possessed within New York City for sale or use, sued a New Mexico retailer that sold cigarettes online to residents in New York City. *Id.* at 4–6, 130 S.Ct. 983. The City alleged that the New Mexico *1250 retailer failed to comply with a federal law requiring out-of-state vendors to submit customer information to the states into which it ships cigarettes. *Id.* at 4, 130 S.Ct. 983. That failure, the City argued, not only made it more difficult for the City to track down people who possessed cigarettes in New York City purchased elsewhere, but also constituted mail and wire fraud under RICO, which caused the City to lose millions of dollars in uncollected per-pack cigarette taxes. *Id.*

The Supreme Court disagreed. It held that the New Mexico retailer’s failure to submit customer information to the State of New York was too attenuated from the City’s loss of cigarette possession tax proceeds to satisfy the proximate cause allegation requirement. See *id.* at 11, 130 S.Ct. 983. The Supreme Court explained that the conduct constituting the alleged fraud was the New Mexico retailer’s failure to submit customer information to the State of New York, but “the conduct directly responsible for the City’s harm was the customers’ failure to pay their taxes.” *Id.* Thus, “the conduct directly causing the harm was distinct from the conduct giving rise to the fraud,” and therefore the City failed to satisfy the Supreme Court’s direct relation requirement. *Id.*

In contrast, in *Bridge v. Phoenix Bond & Indemnity Co.*, the Supreme Court affirmed the Seventh Circuit’s reversal of the district court’s order dismissing the plaintiffs’ complaint for failure sufficiently to allege the proximate cause element under RICO. 553 U.S. 639, 645, 661, 128 S.Ct. 2131, 170 L.Ed.2d 1012 (2008). The plaintiffs were bidders at a county tax lien auction. *Id.* at 643, 128 S.Ct. 2131. To ensure fair distribution of tax liens during the auctions, the county enacted a “Single, Simultaneous Bidder Rule,” requiring each “tax [lien] buying entity” to bid in its own name and not to use agents or employees to submit simultaneous bids on its behalf. *Id.* The plaintiffs alleged that the defendants violated that rule by using agents to submit simultaneous bids on the defendants’ behalf and directing those agents to file false attestations that they had complied with the county’s rules. *Id.* at 643–44, 128 S.Ct. 2131. The plaintiffs alleged that this deceptive practice resulted in the defendants receiving a disproportionately higher share of tax liens at the county auction. *Id.* The plaintiffs further alleged that as a result of this deceptive practice, they were deprived of their ability to obtain their fair share of tax liens at the county auction. *Id.* at 644, 128 S.Ct. 2131.

[11] The defendants countered that the plaintiffs’ alleged harm was too speculative to satisfy RICO’s proximate cause requirement because the defendants misrepresented information to the county, not the plaintiffs. *Id.* at 648, 128 S.Ct. 2131. But a unanimous Supreme Court rejected this argument, noting that proximate cause is “a flexible concept that does not lend itself to a black-letter rule that will dictate the result in every case.” *Id.* at 654, 128 S.Ct. 2131 (internal quotations omitted). Applying its direct relation requirement, the Supreme Court held that the plaintiffs’ “alleged injury—the loss of valuable liens—is the direct result of [the defendants’] fraud. It was a foreseeable and natural consequence of [the defendants’] scheme to obtain more liens for themselves that other bidders would obtain fewer liens.” *Id.* at 658, 128 S.Ct. 2131. And unlike in *Anza* and *Hemi Group*, where other parties suffered more direct injuries than the plaintiffs, in *Bridge*, the county—which sold the tax liens at prices not dependent on who was the buyer—was not injured. *Id.* Rather, the plaintiffs were the immediate victims of the defendants’ fraud and were best situated to sue the defendants. *Id.* Thus, the Supreme Court held that the *1251 plaintiffs had sufficiently alleged proximate cause under RICO. *Id.* at 661, 128 S.Ct. 2131.

[12] Under the Supreme Court’s *Bridge* precedent alone, we think Plaintiffs’ allegations satisfy the Supreme Court’s direct relation requirement. Here, the alleged violation is that Defendants actively concealed *Actos*’s risk of causing bladder cancer to sell more *Actos* to unsuspecting persons, thereby increasing *Actos*’s revenue. And Plaintiffs’ alleged injury is that they purchased *Actos* prescriptions for which they would not have paid had they been warned about *Actos*’s risk of bladder cancer. Because Plaintiffs were immediate victims of Defendants’ alleged fraudulent scheme to conceal *Actos*’s risk of bladder cancer, the alleged RICO violation (conspiracy to commit mail and wire fraud violative of 18 U.S.C. §§ 1341, 1343) has a direct relation to Plaintiffs’ alleged harm.

The *Holmes* factors also weigh in favor of permitting Plaintiffs’ RICO claims to proceed. The first *Holmes* factor tasks us with determining whether it would be too difficult to ascertain what damages are attributable to Defendants’ alleged RICO violation, as opposed to factors other than, and independent of, Defendants’ alleged misrepresentations. 503 U.S. at 269, 112 S.Ct. 1311. While “it is often easier to ascertain the damages that flow from actual, affirmative conduct, than to speculate what damages arose from a party’s failure to act,” *Oregon Laborers-Employers Health & Welfare Trust Fund v. Philip Morris Inc.*, 185 F.3d 957, 965 (9th Cir. 1999) (internal quotation marks omitted), we are not persuaded that it is so difficult here that Plaintiffs should be denied the opportunity to prove their damages.⁷ We leave it to the district court on remand to assess Plaintiffs’ damages, if the litigation proceeds to that phase.

[13] Second, we consider the risk of multiple recoveries by plaintiffs at different levels of injury from the defendants’ acts. *Holmes*, 503 U.S. at 269, 112 S.Ct. 1311. Here, like in *Bridge*, and unlike in *Anza* and *Hemi Group*, there is no concern of “duplicative recoveries by plaintiffs removed at different levels of injury from the violation.” *Bridge*, 553 U.S. at 658, 128 S.Ct. 2131. It is each individual plaintiff who paid out money for *Actos* prescriptions who now seeks recovery of those payments. As we read Plaintiffs’ complaint, the damages suffered by Patients and Painters Fund do not overlap, as it appears that Patients seek to recover only the dollars they paid for *Actos* out-of-pocket, for which they have not been reimbursed by a TPP.⁸ Further, Plaintiffs’ putative class expressly excludes individuals *1252 who are pursuing personal injury claims, so there is no risk that some plaintiffs will receive overlapping economic and personal injury damages.

[14] Finally, under the third *Holmes* factor, we consider whether holding Defendants liable in this case justifies the general interest of deterring injurious conduct or whether there are more directly injured victims we can count on to hold Defendants liable. 503 U.S. at 269–70, 112 S.Ct. 1311. Here, patients and TPPs who paid money for *Actos* are the most direct victims of those who suffered economic injury. Although people who ingested *Actos* and developed bladder cancer suffered an additional and greater harm than others who paid for *Actos* but did not develop bladder cancer, this does not change the fact that all patients and TPPs who paid for *Actos* on the premise that it did not cause an increased risk of bladder cancer were allegedly defrauded by Defendants and suffered the same direct economic injury: payments for a drug which would not have been purchased if suitably described. Additionally, others may have been affected by Defendants’ alleged fraud. For instance, prescribing physicians who prescribed *Actos* for their patients may have watched their patients develop bladder cancer. But as far as we can tell from Plaintiffs’ complaint, prescribing physicians did not suffer an economic injury. Thus, holding Defendants liable for Plaintiffs’ alleged injuries advances the interest in deterring injurious conduct, without including others who did not suffer direct out-of-pocket losses.

2. Circuit Court Precedent

While our court has recognized the Supreme Court’s direct relation requirement and *Holmes* factors for RICO proximate cause in several cases, *see, e.g., Harmoni International Spice, Inc. v. Hume*, 914 F.3d 648 (9th Cir. 2019); *Canyon County*, 519 F.3d at 972; *Oregon Laborers*, 185 F.3d at 963–66,⁹ we have never applied it *1253 to the situation at issue here—whether patients and TPPs suing pharmaceutical companies for concealing an allegedly known safety risk about a drug can satisfy RICO’s proximate cause requirement.¹⁰ But several of our sister circuits have addressed this question in similar factual scenarios and have reached different results, creating an apparent inter-circuit split. We look to their reasoning for guidance.

a. Seventh Circuit

In *Sidney Hillman Health Center v. Abbott Laboratories*, two TPPs who had paid to cover their patients’ off-label¹¹ uses of a prescription drug named *Depakote* sued the drug manufacturer under RICO for concealing its role in

promoting *Depakote*'s off-label uses to intermediaries, such as prescribing physicians. 873 F.3d 574, 575 (7th Cir. 2017). In relevant part, the district court dismissed the TPPs' complaint for failure to allege that their damages were proximately caused by the drug manufacturer's concealed off-label promotion, and the Seventh Circuit affirmed. *Id.* at 575, 578.

The Seventh Circuit first noted that, in some cases, an injury to one person caused by wrongs against another can satisfy RICO's proximate cause requirement, as *1254 the Supreme Court held in *Bridge*, 553 U.S. at 661, 128 S.Ct. 2131. 873 F.3d at 576. However, the Seventh Circuit held that the TPPs in *Sidney Hillman* were too far removed from the alleged RICO violation to satisfy the proximate cause requirement. *Id.* The Seventh Circuit opined that while TPPs "part with money ... it is not at all clear that they are the initially injured parties, let alone the sole injured parties." *Id.* The Seventh Circuit explained that patients may be the most directly injured parties, as they incurred financial loss (if they paid a copayment to receive *Depakote*) and personal injury damages if they suffered harmful effects from using *Depakote* for an unsafe off-label use. *Id.* Moreover, the Seventh Circuit noted, the "patients' health and financial costs come first in line temporally; that pharmacies then send bills to [TPPs], which cover the remainder of the expense, does not make those [TPPs] the initial losers" from the drug manufacturer's unlawful promotion scheme. *Id.* The Seventh Circuit opined that prescribing physicians may also suffer loss, though indirectly, because "[i]f a physician prescribes an ineffective medicine and so does not provide [patients] help, patients may turn elsewhere." *Id.*

The Seventh Circuit next explained that physicians make independent decisions when prescribing patients medicine, and it would be difficult to disentangle which physicians' decisions, if any, were influenced by the drug manufacturer's unlawful promotions. *Id.* at 577–78. That, and other factors, such as the fact that some patients may have benefited from using *Depakote* for an off-label use, convinced the Seventh Circuit that it would be too difficult to calculate the plaintiffs' alleged damages. *Id.* Thus, the Seventh Circuit held that the TPPs—"several levels removed in the causal sequence" from the drug manufacturer's actions—could not satisfy RICO's proximate cause requirement. *Id.* at 576–78.

Similarly, in *UFCW Local 1776 v. Eli Lilly & Co.*, TPPs and individual patients brought a putative class action for civil RICO fraud against the manufacturer of the drug *Zyprexa*, alleging that the manufacturer misrepresented *Zyprexa*'s side effects and effectiveness to physicians and promoted *Zyprexa* for off-label uses when there was no evidence that *Zyprexa* was effective for off-label uses. 620 F.3d 121, 123, 129 (2d Cir. 2010). The plaintiffs alleged two damages theories: (1) the "excess price theory"—that they overpaid for *Zyprexa* prescriptions because the manufacturer relied on its misrepresentations to charge higher prices; and (2) the "quantity effect theory"—that they paid for *Zyprexa* prescriptions "that would not have been issued but for the alleged misrepresentations." *Id.* The district court certified a class of TPPs based upon their excess price theory for damages, but the Second Circuit reversed. *Id.* at 123, 137.

As to the proximate cause requirement under RICO, the Second Circuit held that the plaintiffs' injuries under both of their damages theories were too attenuated, as they "rest[] on the independent actions of third and even fourth parties." *Id.* at 134 (quoting *Hemi Group*, 559 U.S. at 15, 130 S.Ct. 983). The Second Circuit was not persuaded by the plaintiffs' argument that "the ultimate source for the information on which doctors based their prescribing decisions was [the manufacturer] and its consistent, pervasive marketing plan," because the manufacturer was "not ... the *only* source of information on which doctors based prescribing decisions." *Id.* at 135 (emphasis in original). Rather, "[a]n individual patient's diagnosis, past and current medications being taken by the patient, *1255 the physician's own experience with prescribing *Zyprexa*, and the physician's knowledge regarding the side effects of *Zyprexa* are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by [the manufacturer]." *Id.* Accordingly, the Second Circuit held that the plaintiffs failed to allege that their damages were proximately caused by the drug manufacturer's wrongful conduct and reversed the district court's certification order. ¹² *Id.* at 134, 136; see also *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 90–91 (2d Cir. 2015) (holding that the plaintiff's RICO claims were foreclosed by *UFCW Local 1776*, 620 F.3d at 121).

c. First Circuit

To the contrary, in *In re Neurontin Marketing & Sales Practices Litigation*, a jury awarded Kaiser Foundation

b. Second Circuit

Health Plan (“Kaiser”), a TPP, damages for the injury it suffered in paying for off-label [Neurontin](#) prescriptions that were induced by Pfizer’s (the drug manufacturer) fraudulent scheme to misrepresent [Neurontin’s effectiveness for off-label conditions](#). 712 F.3d 21, 25–26 (1st Cir. 2013). The district court had found that Kaiser relied on Pfizer’s fraudulent marketing campaign in deciding to include [Neurontin](#) in its formulary—a list of medications its treating physicians were authorized to prescribe. *Id.* at 28–29. The district court subsequently denied Pfizer’s motion for a new trial, and Pfizer appealed. *Id.* at 27.

Pfizer argued that Kaiser could not satisfy RICO’s proximate cause requirement as a matter of law. *Id.* at 34. But the First Circuit disagreed, holding that “Kaiser has met both the direct relationship and functional tests articulated in [Holmes](#) and its progeny.” *Id.* at 38. Unlike the Second and Seventh Circuits, the First Circuit rejected the argument that there were “too many steps in the causal chain between [Pfizer’s] misrepresentations and Kaiser’s alleged injury” to meet the “direct relation” requirement. *Id.* Rather, the First Circuit held that “the causal chain in this case is anything but attenuated,” because Pfizer “has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed.” *Id.* at 38–39. Pfizer’s fraudulent marketing scheme, which was meant to increase its sales and profits, “only became successful once Pfizer received payments for the additional [Neurontin](#) prescriptions it induced.” *Id.* at 39. Those payments came from TPPs, including Kaiser. *Id.*

The First Circuit also rejected Pfizer’s argument that “because doctors exercise independent medical judgment in making decisions about prescriptions, the actions of these doctors are independent intervening causes” that cut off the chain of causation. *Id.* The First Circuit explained that “Pfizer’s scheme relied on the expectation that physicians would base their prescribing decisions in part on Pfizer’s fraudulent marketing.” *Id.* “The fact that some physicians may have considered factors other than Pfizer’s detailing materials in making their prescribing decisions does not add such attenuation to the causal chain as to eliminate proximate cause”; rather, “[t]his is a damages question” about the “total number of prescriptions that were attributable to Pfizer’s actions.” *Id.* Finally, the *1256 First Circuit noted that “[h]olding Pfizer liable will have an effect in deterring wrongful conduct,” and thus it held that Kaiser had satisfied the proximate cause requirement under RICO. *Id.* at 39–40.

d. Third Circuit

Similarly, in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, the Third Circuit held that the TPP plaintiffs sufficiently alleged proximate cause for their civil RICO claims. 804 F.3d 633, 634 (3d Cir. 2015). There, TPPs filed a putative class action against the defendant alleging under RICO that the defendant misrepresented significant heart-related safety risks associated with the drug [Avandia](#). *Id.* at 634–36. The plaintiffs alleged that they included [Avandia](#) in their formularies and covered it at favorable rates for their members in reliance on the defendant’s misrepresentations about [Avandia’s](#) safety. *Id.* at 636. The plaintiffs also alleged that physicians relied on the defendant’s misrepresentations in deciding to prescribe [Avandia](#) and that they would have prescribed it to fewer patients if the defendant had not concealed its safety risks. *Id.* The district court held that the plaintiffs adequately alleged that the defendant proximately caused their damages but certified its decision for interlocutory appeal. *Id.* at 637.

The Third Circuit affirmed. Applying the Supreme Court’s direct relation requirement, the Third Circuit held that “[t]he conduct that allegedly caused [the] plaintiffs’ injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint—the misrepresentation of the heart-related risks of taking [Avandia](#) that caused TPPs ... to place [Avandia](#) in the formulary.” *Id.* at 644. Next, looking to the [Holmes](#) factors, the Third Circuit noted that it would not be too difficult to distinguish between the damages attributable to the defendant’s alleged violation from other independent factors, and that at the pleadings stage, the question of damages was “a question for another day.” *Id.* Further, the Third Circuit observed that the plaintiffs were best situated to sue, as the plaintiffs’ alleged injury “is an economic injury independent of any physical injury suffered by [Avandia](#) users,” and “prescribing physicians did not suffer RICO injury from [the defendant’s] marketing of [Avandia](#).” *Id.*

The Third Circuit, like the First Circuit, rejected the defendant’s argument that “the presence of intermediaries, doctors and patients, destroys proximate cause because they were the ones who ultimately decided whether to rely on [the defendant’s] misrepresentations.” *Id.* at 645. The Third Circuit explained that “drug manufacturers are well aware that TPPs cover the cost of their drugs” and the defendant’s “fraudulent scheme could have been successful only if [the] plaintiffs paid for [Avandia](#), [which] is the very injury that [the]

plaintiffs seek recovery for.” *Id.* Thus, the plaintiffs’ alleged injury had a direct relation to the alleged RICO violation. *Id.* Therefore, the Third Circuit affirmed the district court’s holding that the plaintiffs adequately alleged RICO proximate cause at the pleadings stage. *Id.* at 645–46.

e. Circuit Court Precedent Analysis

Although each of these four circuit court opinions arises under similar factual scenarios, factual and procedural distinctions exist between them. For example, the Third and Seventh Circuits’ opinions confronted the issue whether the plaintiffs could satisfy the proximate cause requirement under RICO at the pleadings stage, whereas the Second Circuit considered the issue at the class certification stage, and the Third Circuit reviewed the issue post-trial. *1257 Further, while the Second, Third, and Seventh Circuit cases involved putative class actions, the First Circuit’s opinion involved a single TPP. But these minor factual and procedural differences do not help us resolve the central dispute between the Second and Seventh Circuits’ reasoning and the First and Third Circuits’ reasoning.

Indeed, it seems the central dispute between the Second and Seventh Circuits and the First and Third Circuits is whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP. 13 We think the First and Third Circuits have it right because their reasoning is more consistent with the Supreme Court’s direct relation requirement.

In this case, although prescribing physicians serve as *intermediaries* between Defendants’ fraudulent omission of *Actos*’s risk of causing bladder cancer and Plaintiffs’ payments for *Actos*, prescribing physicians do not constitute an *intervening cause* to cut off the chain of proximate cause. An intervening cause is “a later cause of independent origin that was not foreseeable.” *Mendez v. County of Los Angeles*, 897 F.3d 1067, 1081 (9th Cir. 2018) (quoting *Exxon Co. v. Sofec*, 517 U.S. 830, 837, 116 S.Ct. 1813, 135 L.Ed.2d 113 (1996)). Here, since *Actos* was a *prescription* drug, it was *required* to be prescribed by physicians. Hence, it was perfectly foreseeable that physicians who *prescribed Actos* would play a causative role in Defendants’ alleged fraudulent scheme to increase *Actos*’s revenues. Further, “because of the structure of the American health care system,” Defendants have always known that “physicians would not be the ones

paying for the drugs they prescribed.” *Neurontin*, 712 F.3d at 38–39. Rather, they are well aware that TPPs and individual patients pay for the drugs. See *Avandia*, 804 F.3d at 645. Defendants’ alleged fraudulent marketing scheme, which was intended to increase *Actos*’s sales, “only became successful once [they] received payments for the additional [Actos] prescriptions [they] induced”—the very injury for which Plaintiffs seek recovery. *Neurontin*, 712 F.3d at 39. This is consistent with the Supreme Court’s requirement that the proximate cause inquiry focus on the direct relation between the alleged violation and alleged injury. *Hemi Group*, 559 U.S. at 12, 130 S.Ct. 983.

If we were to hold the opposite—that prescribing physicians’ and pharmacy benefit managers’ decisions constitute an intervening cause to sever the chain of proximate cause—as the Second and Seventh Circuits have held, drug manufacturers would be insulated from liability for their fraudulent marketing schemes, as they could continuously hide behind prescribing physicians and pharmacy benefit managers. That is not the purpose the requirement *1258 of proximate cause is intended to serve. Proximate cause exists to “limit a person’s responsibility for the consequences of that person’s own acts.” *Holmes*, 503 U.S. at 268, 112 S.Ct. 1311. Here, Plaintiffs seek to hold Defendants liable for the consequences of their own acts and omissions toward Plaintiffs: the money spent by Plaintiffs to purchase *Actos*.

There is also a difference between fraudulent promotion of “off-label” uses for a prescription drug as in *Sidney Hillman*, 873 F.3d at 575 and *UFCW Local 1776*, 620 F.3d at 127, and fraudulent failure to warn of a drug’s known risk of causing bladder cancer, as in this case.

It was recognized in both *Sidney Hillman* and *UFCW Local 1776* that the drug manufacturer’s fraudulent promotion of a prescription drug for off-label uses was not the *only* basis upon which the prescribing physicians relied in prescribing the drug. In *Sidney Hillman*, the Seventh Circuit noted that it would be too difficult to disentangle which physicians’ prescribing decisions, if any, were influenced by the defendants’ unlawful promotion of the prescription drug for off-label uses. 873 F.3d at 577–78. Similarly, in *UFCW Local 1776*, the Second Circuit noted that the drug manufacturer’s unlawful promotion of the prescription drug for off-label uses was not the only source of information upon which the prescribing physicians based their decisions to prescribe the drug. 620 F.3d at 135.

Echoing the first factor of *Holmes*, the failure to warn of the bladder cancer risk in this case makes Plaintiffs' damages more clearly "attributable to [Defendants'] violation." 503 U.S. at 269, 112 S.Ct. 1311. The damages claimed from off-label uses in *Sidney Hillman* and *UFCW Local 1776* are less directly attributable to the alleged false promotions. It is much more likely that Actos's risk of causing a disease as serious as bladder cancer would materially influence prescribing physicians' decisions whether to prescribe Actos. Plaintiffs' allegations confirm this theory, as they allege that a survey conducted by Defendants in 2003 showed that 75% of surveyed physicians' interest in a different oral anti-diabetic drug declined "greatly" once they learned that it carried a risk of causing bladder cancer. Further, Plaintiffs allege that those survey results are confirmed by their allegation that sales of Actos decreased approximately 80% once the FDA issued its official warning that Actos may be linked to bladder cancer in patients who use it over a prolonged period of time. Taking those allegations as true, as we must, the question whether prescribing physicians would not have been influenced by Defendants' alleged fraudulent omission is less concerning in this case than it was to the Second and Seventh Circuits.

Moreover, the Seventh Circuit's distinction that TPPs' injuries are too far removed from the drug manufacturer's fraudulent scheme to satisfy the RICO proximate cause requirement because they are not "the sole injured parties" and because individual patients' "health and financial costs come first in line temporally" misses the mark. *Sidney Hillman*, 873 F.3d at 576. The Supreme Court has never made a distinction about temporal proximity of the plaintiffs to the damages caused to others when evaluating whether a plaintiff has adequately alleged that the defendant proximately caused the plaintiff's damages under RICO. Additionally, the fact that individual patients and TPPs both suffered economic injuries from a drug manufacturer's fraudulent scheme does not mean that one group of plaintiffs should be favored to recover over the other, so long as they both suffered the same economic injuries from the drug manufacturer's *1259 same misconduct. Finally, the Seventh Circuit's comment that prescribing physicians may suffer indirect loss does not attenuate the chain of causation so far as to break it. See *id.* Even if prescribing physicians suffer an indirect loss such as reputational harm for prescribing an ineffective or unsafe drug, they are not out of pocket for the price of the drug and thus do not suffer the same economic loss as do individual patients and TPPs. For these reasons, we agree with the First and Third Circuits that Plaintiffs' damages are not too far removed from Defendants' alleged omissions

and misrepresentations to satisfy RICO's proximate cause requirement.

3. Reliance

As a threshold matter, any argument that Patients have not alleged that they relied on Defendants' misrepresentations and omissions lacks merit. Each patient alleged that had he "known that Actos increased the risk of causing bladder cancer, he would never have purchased and ingested the drug." Additionally, Patients alleged that they "relied on Defendants' ... misrepresentations of Actos[s] safety in purchasing the drug." These statements are sufficient to allege that Patients relied on Defendants' misrepresentations.

Next, the Supreme Court has explained that if there is a direct relationship between a defendant's wrongful conduct and a plaintiff's alleged injury, a RICO plaintiff who did not directly rely on the defendant's omission or misrepresentation can still satisfy the requirement of proximate causation of damages. Recall that in *Bridge* the defendants' misrepresentations that they complied with the county's "Single, Simultaneous Bidder Rule" were made to the tax lien selling county, not to the plaintiff tax lien buyers. 553 U.S. at 648, 128 S.Ct. 2131. But the Supreme Court held that it was sufficient to establish proximate cause between the defendants' alleged wrongful conduct and the plaintiffs' alleged injury that the county had relied on the defendants' false attestations. See *id.* at 658–59, 128 S.Ct. 2131. What mattered most in the RICO proximate causation inquiry was whether there was a direct relationship between the alleged RICO violation and the plaintiffs' alleged injury. See *id.* And there was. The plaintiffs' "alleged injury—the loss of valuable [tax] liens—[was] the direct result of ... [the defendants'] scheme to obtain more liens for themselves." *Id.* at 658, 128 S.Ct. 2131.

In so holding, the Supreme Court expressly rejected the defendants' argument that "[direct] reliance is an element of a civil RICO claim predicated on mail fraud." 553 U.S. at 646–49, 128 S.Ct. 2131. The Supreme Court explained that the civil RICO statute has no reliance requirement on its face, and a person may be injured "by reason of" another person's fraud even if the injured party did not rely on any misrepresentation. *Id.* at 648–49, 128 S.Ct. 2131. Nonetheless, the Supreme Court noted that it "may well be that a RICO plaintiff alleging injury by reason of a pattern of mail fraud must establish at least [indirect] reliance in order to prove causation." 553 U.S. at 658–59, 128 S.Ct. 2131. This is because, logically, a plaintiff cannot even establish but-for causation if *no one* relied on the defendant's alleged misrepresentation. *Id.*

Despite this precedent, Defendants argue that Painters Fund failed to allege reliance on Defendants' omissions of *Actos's* bladder *cancer* risk, since Painters Fund expressly alleged that, as a TPP, it "relies on [its] members and their prescribers to make informed decisions about which drugs will be prescribed and, in turn, submitted to Plaintiff Painters Fund for reimbursement." This argument is also *1260 meritless. Like in *Bridge*, where it was sufficient to satisfy RICO's proximate cause requirement that the county (a third party) had relied on the defendants' false attestations, here, it is sufficient to satisfy RICO's proximate cause requirement that Painters Fund alleged that prescribing physicians (also third parties, but not intervening causes) relied on Defendants' misrepresentations and omissions.

Finally, Defendants argue that even if Painter's Fund has alleged indirect reliance, its general allegations of indirect reliance—i.e., that prescribing physicians relied on Defendants' misrepresentations and omissions in prescribing *Actos* for their patients, which Painters Fund then reimbursed—are insufficient, because Painters Fund should have alleged with specificity exactly which prescribing physicians were misled by Defendants' alleged misrepresentations. Remembering that this case is before us at the pleadings stage and without the benefit of discovery, we recognize

that it would be difficult for Painters Fund to determine with specificity exactly which doctors relied on Defendants' alleged misrepresentations. All that is required of Painters Fund at this stage is to allege that *someone* in the chain of causation relied on Defendants' alleged misrepresentations and omissions, which it has done here. Thus, we hold that Plaintiffs have adequately alleged the reliance necessary to satisfy RICO's proximate cause requirement.

III. CONCLUSION

While we express no opinion on Plaintiffs' chances of success in this litigation as it proceeds, we hold that Plaintiffs have satisfactorily alleged that Defendants proximately caused their claimed damages at the pleadings stage. We reverse the district court's judgment dismissing Plaintiffs' RICO claims under *Rule 12(b)(6)* for lack of RICO standing, and we remand to the district court for further proceedings consistent with this disposition.

All Citations

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Footnotes

- * Judge Watford was drawn to replace Judge Rawlinson. Judge Watford has read the briefs, reviewed the record, and watched the recording of oral argument held on June 6, 2019.
- 1 No argument has yet been made in this action that the settlement encompassed the plaintiffs' RICO claims or mooted them.
- 2 Prime Therapeutics, LLC is not a party to this litigation and is not discussed elsewhere in the complaint.
- 3 Plaintiffs originally alleged a second damages theory—that they overpaid for *Actos* prescriptions because Defendants inflated the price of *Actos* under the guise that *Actos* did not increase a person's risk of developing bladder cancer—called the "excess price theory." But Plaintiffs have abandoned their excess price theory for damages on appeal.
- 4 Plaintiffs also brought claims under state consumer protection laws of California, Florida, Massachusetts, Minnesota, Missouri, and New Jersey. In a separate order, the district court dismissed all of Plaintiffs' state law claims. With the exception of their Massachusetts claim, Plaintiffs also appeal the dismissal of their state law claims. We address those claims in a concurrently filed memorandum disposition.
- 5 To recover for a civil RICO violation, "a plaintiff must prove that the defendant engaged in (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Chaset v. Fleer/Skybox Int'l, LP*, 300 F.3d 1083, 1086 (9th Cir. 2002) (citing 18 U.S.C. § 1962).
- 6 Defendants do not argue in this appeal that Plaintiffs' allegations fail to allege but-for causation.
- 7 We note that Defendants' argument that had Plaintiffs not taken *Actos*, they would have paid for an alternative drug to treat their *type 2 diabetes*, has not fallen on deaf ears. It seems quite logical that Plaintiffs would have paid for a different drug to treat patients' *diabetes* had they known that *Actos* increases a person's risk of developing bladder *cancer*. But at this stage in the proceedings, we take Plaintiffs' allegations that they would not have bought or paid for *Actos* as true. *Bain*, 891 F.3d at 1211. Plaintiffs do not allege that they would have paid for an alternative *diabetes* drug had they known *Actos* carries an increased risk of causing bladder *cancer*. Further, if what Defendants argue proves true, Plaintiffs may

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still be entitled to damages if the alternative drugs they would have paid for cost less than [Actos](#). Plaintiffs have alleged there are at least three less expensive alternatives to [Actos](#), and discovery may prove Plaintiffs were likely to have bought these alternatives. In any event, this is a damages question for another day.

8 Of course, on remand, if discovery reveals that Patients' claimed damages overlap with damages claimed by Painters Fund or another TPP, Plaintiffs should not recover any overlapping damages.

9 [Oregon Laborers](#), the case most closely related to the present action in this circuit to date, is distinguishable. There, six employee health and welfare benefit plans sued tobacco companies and public relations companies under federal RICO and other antitrust and state laws. [185 F.3d at 961](#). The plaintiffs alleged that the defendants conspired to persuade the public that scientific studies linking smoking to health risks were not accurate and that the connection between smoking and disease was merely an "open controversy." *Id.* The plaintiffs alleged that this wrongful conduct "resulted in more smoking, less quitting, and smoking of more hazardous cigarettes" among their plan participants, which then resulted in more disease among their plan participants who smoked. *Id.* at 962. In turn, the plaintiffs alleged, they suffered higher expenditures to cover their plan participants' medical bills. *Id.*

The district court held that the plaintiffs failed to state a RICO claim for relief under [Rule 12\(b\)\(6\)](#), and we affirmed. *Id.* at 961. We held that the plaintiffs' alleged injury was "indirect" and too remote to satisfy RICO's proximate cause requirement. *Id.* at 963. We explained that "all of [the] plaintiffs' claims rely on alleged injury to smokers—without any injury to smokers, [the] plaintiffs would not have incurred the additional expenses in paying for the medical expenses of those smokers." *Id.* (second emphasis added). Instead of the plaintiffs, we reasoned, the smokers were the direct victims of the defendant's alleged wrongful conduct. *Id.* at 964. Thus, under the Supreme Court's direct relation requirement, we held that the alleged RICO violation was distinct from the plaintiffs' alleged injury. See *id.* at 963–64. Therefore, the plaintiffs failed to allege that their damages were proximately caused by the defendants' actions. See *id.* at 966.

Plaintiffs' alleged injury in this case is distinct from the plaintiffs' alleged injury in [Oregon Laborers](#). There, the chain of causation from the defendant's alleged misrepresentation to the plaintiffs' alleged injury depended upon an independent link that required the smokers to develop illnesses that necessitated medical treatment, for which the plaintiffs then paid. But here, Plaintiffs' alleged injury is directly related to Defendants' alleged misrepresentations, as they allege that they paid money out-of-pocket for [Actos](#), which they otherwise would not have paid had Defendants not fraudulently omitted [Actos's](#) risk of causing bladder cancer. Whether Plaintiffs developed bladder cancer is irrelevant to their claims. Thus, [Oregon Laborers](#) is distinguishable and does not control here.

10 The Seventh Circuit once commented that the Ninth Circuit "deem[s] this [issue] so straightforward that [it] ha[s] issued nonprecedential decisions" about it. [Sidney Hillman Health Ctr. v. Abbott Labs.](#), 873 F.3d 574, 578 (7th Cir. 2017). Not quite. Rather, in [In re Actimmune Marketing Litigation](#), we summarily affirmed the district court's dismissal without prejudice of the plaintiffs' RICO claims where the district court held in part that the plaintiffs' complaint failed sufficiently to plead proximate cause for their civil RICO claim for lack of specificity under [Federal Rule of Civil Procedure 8\(a\)](#). 464 F. App'x 651 (9th Cir. 2011) (citing [In re Actimmune Mktg. Litig.](#), 614 F. Supp. 2d 1037, 1050–51 (N.D. Cal. 2009)). When the plaintiffs filed their amended complaint, they abandoned their RICO claims. See [In re Actimmune Mktg. Litig.](#), No. C 08-02376 MHP, 2009 WL 3740648, at *1 (N.D. Cal. Nov. 6, 2009). Our summary affirmance of the district court's decision to dismiss the plaintiffs' RICO claims without prejudice can hardly be considered a decision on the merits of the issue that we deemed "so straightforward" as to issue a non-binding decision.

In [United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.](#), the plaintiffs sued Amgen, Inc. for concealing adverse test results about a drug's off-label uses. 400 F. App'x 255, 257 (9th Cir. 2010). We held that the plaintiffs' complaint failed to identify false statements or material omissions that Amgen made about the drug's safety. *Id.* Further, we held that the plaintiffs failed to plead a cognizable theory of proximate cause for their civil RICO claim because the complaint "proffered an attenuated causal chain that involved at least four independent links"—(1) the United States Pharmacopeia-Drug Information ("USP-DI")'s listing of the drug to be used for a certain off-label use; (2) Medicare's decision to cover the drug for that off-label use; (3) third-party payors' decision to cover the drug for the off-label use; and (4) doctors' decisions to prescribe the drug for the off-label use. *Id.* But we never independently addressed whether patients and TPPs can meet RICO's proximate cause requirement under the Supreme Court's direct relation requirement and [Holmes](#) factors to hold pharmaceutical companies liable for mail and wire fraud. Further, our present case does not require as many causal links. And of course, because unpublished dispositions from our circuit are not precedential, see [Ninth Circuit Rule 36-3\(a\)](#), we are free to decide this issue in the first instance.

11 "Off-label" refers to using a drug to treat conditions other than those it was originally developed to treat.

12 The Second Circuit remanded, however, for the district court to consider individual claims based upon the plaintiffs' quantity effect damages theory. [UFCW Local 1776](#), 620 F.3d at 136. The Second Circuit noted that "while that theory

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cannot support class certification, it is not clear that the theory is not viable with respect to individual claims by some TPPs or other [individual] purchasers.” *Id.*

- 13 We note that all four of our sister circuits’ opinions may support the claims by individual patients who are plaintiffs in this case, not just the First and Third Circuits’ opinions. In *Sidney Hillman*, in holding that *TPPs* are too far removed from the drug manufacturer’s alleged wrongful conduct to satisfy the RICO proximate cause requirement, the Seventh Circuit implied that *individual patients* may be able to satisfy the proximate cause requirement, as they are the most directly injured party whose “health and financial costs come first in line temporally.” 873 F.3d at 576. And in *UFCW Local 1776*, although the Second Circuit reversed the district court’s class certification order because the plaintiffs could not satisfy RICO’s proximate cause requirement as a class, it remanded to the district court to consider in the first instance individual plaintiffs’ claims based upon the quantity effect damages theory. 620 F.3d at 136.

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